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Nellcor

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Dear -----,

This letter clarifies existing N400 instructions for use and introduces additional changes to the clinical management protocol. These clarifications and changes are the result of thirteen reports of poor neonatal outcomes including two stillbirths, low Apgar scores, acidosis, and transient neonatal depression when the N400 was used. This letter is intended to strongly reemphasize the recommended management protocol for use with fetal pulse oximetry and to add additional recommendations which we think will be helpful to the clinician. These clarifications and changes are as follows:

1. The definition of "ominous" has been broadened from the original definition and is discussed below. If the fetal heart rate (FHR) pattern is "ominous," even in the presence of a normal fetal oxygen saturation (FSpO2) value, the clinician should deliver the fetus.

2. In situations where an FSpO2 signal is not present, and efforts to readjust the monitor fail to restore the signal, clinical management should be based on available data, e.g. FHR. No inferences regarding fetal status should be made on the basis of earlier FSpO2 values.

3. Because the N400 is only an *adjunct* to conventional fetal heart monitoring, use of the N400 is not a substitute for clinical interpretation of FHR.

4. The FHR classification and clinical management protocol matrix should be considered recommendations only and may not apply in every case.

Explanation for Changes to N400 Clinical Users Guide

Definition of "ominous" FHR

During the U.S. Multi-center Randomized Controlled Trial of the N400, the management protocol defined an ominous FHR pattern as:

- Prolonged deceleration to < 70 bpm for > 7 minutes

Experience over the past two years suggests that the definition of "ominous" FHR pattern should be expanded to include additional patterns seen in conditions of significant metabolic acidosis, even when FSpO2 appears reassuring. This allows intervention in situations of profound acidosis (hemodynamic compromise) at a time when the fetus is normally oxygenated.

The Fetal Heart Rate Classification (Table 1) has been modified to include two additional FHR patterns under the definition of "ominous" and to qualify the definition of prolonged deceleration. Under the new classification, ominous patterns are defined as:

- Prolonged deceleration to < 70 bpm for > 7 minutes[FN]
- Markedly decreased to absent variability with persistent late decelerations, or
- Markedly decreased to absent variability with severe variable decelerations.

The following footnote has been added to the FHR Classification to clarify that early intervention for a potentially ominous FHR is appropriate:

> [FN]It is not necessary to wait for more than 7 minutes of prolonged deceleration before initiating intervention (e.g. evaluation of the cause, non-surgical interventions, and preparation for delivery), even with reassuring FSpO2.

When FSpO2 is not Available

When FSpO2 is not available despite sensor adjustment, the device has no adjunctive value. The fetus should be managed as though the FSpO2 were non-reassuring – that is, by FHR and clinical signs alone. No inferences regarding fetal status should be made on the basis of earlier FSpO2 values.

Emphasis on Adjunctive Role of FSpO2

FSpO2 is an instantaneous measure of fetal *oxygenation* and is valid only at the time of the measurement. Furthermore, FSpO2 is *not* a measure of fetal arterial blood pH.

It is possible that a fetus in labor may have experienced a period of significant hypoxia or ischemia prior to the initiation of monitoring. Metabolic acidosis may have occurred as a result of that exposure. If the conditions that caused the prior hypoxia have resolved, subsequent FSpO2 monitoring may be normal although the fetus may remain acidotic and the FHR non-reassuring. The reason for this is that fixed lactic acid may not clear the fetal system for a period of several hours.

Therefore, FSpO2 should only be used as an adjunct to FHR monitoring and other conventional clinical observations during labor. It should never be used as the sole means of assessing fetal status.

Recommended FHR Classification and Clinical Management Protocol Matrix

Tables 1 and 2 in the Enclosure are the updated clinical guidelines for using the N400. These guidelines were developed for the 1100-subject, multi-center, U.S. randomized clinical trial of the N400 and also apply to commercial use of the device.

Clinicians should view Table 2 as recommendations that have been tested clinically, but which may not apply to every clinical situation. They are not intended to substitute for clinical judgment.

We hope that these clarifications are helpful to you in using the N400 system. If you have any questions about FHR classification and the use of fetal pulse oximetry, please contact your local Perinatal Clinical Consultant, or Technical Services (1-800-NELLCOR, press 3).

Sincerely,

Madeleine Bolling
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Tyco Healthcare

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Medical Advisor
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Table 1: Fetal Heart Rate Classification

FHR Class	FHR Pattern
I	REASSURING Any FHR pattern that does not meet criteria for Class II or III. Typically, a Class I trace is characterized by a baseline between 110 and 160 bpm, with longterm variability between 5 and 25 bpm, and either no decelerations or only early decelerations.
II	NONREASSURING Any one of the following for more than 15 minutes: • Persistent late decelerations (> 50% of contractions) • Sinusoidal pattern[a] • Variable decelerations with one or more of the following: - A relative drop of ≥ 70 bpm or an absolute drop to ≤ 70 bpm for more than 60 seconds[b] - Persistent slow return to baseline - Long term variability < 5 bpm[c] - Tachycardia > 160 bpm • Recurrent prolonged decelerations (2 or more < 70 bpm for more than 90 seconds) Any one of the following for more than 60 minutes • Tachycardia >160 bpm with longterm variability < 5 bpm[c] • Persistent decreased variability (≤ 5 bpm for more than 60 minutes)[c]
III	OMINOUS • Prolonged deceleration to < 70 bpm for more than 7 minutes[d] • Markedly decreased or absent variability with persistent late decelerations • Markedly decreased or absent variability with severe variable decelerations

a. Sinusoidal pattern is defined as regular oscillations about the baseline, 5-15 bpm in magnitude, with 2 to 5 cycles per minute on an otherwise normal baseline with absent short-term variability.
b. Variable decelerations are to be timed from the beginning of the deceleration to the end of the deceleration (i.e., more than 60 seconds in duration).
c. Decreased variability not otherwise explained by the clinical situation (e.g. narcotic administration).
d. It is not necessary to wait for more than 7 minutes of prolonged deceleration before initiating intervention (e.g. evaluation of the cause, non-surgical intervention, and preparation for delivery), even with reassuring FSpO2.

Table 2: Clinical Management Protocol Matrix

This matrix includes recommendations that have been tested clinically, but which may not apply to every clinical situation. They are not intended to substitute for clinical judgment.

FHR Classification Group	**FHR and Oximeter**		
	FSpO2 Not Reassuring[a]	FSpO2 Not Available Despite Sensor Adjustment	FSpO2 Reassuring[b]
Class I – Reassuring FHR Pattern	Continue labor unless otherwise indicated[c]	Continue labor unless otherwise indicated[c]	Continue labor unless otherwise indicated
Class II – Nonreassuring FHR Pattern	Evaluate and manage nonreassuring FHR[c]	Evaluate and manage nonreassuring FHR[c]	Continue to labor unless otherwise indicated[c]
Class III – Ominous FHR Pattern	Deliver	Deliver	Deliver

a. FSpO2 Not Reassuring – FSpO2 remains below 30% between contractions or no value available, despite sensor adjustment.
b. FSpO2 Reassuring – FSpO2 returns to a value ≥ 30% between contractions.
c. All corrective, non-operative interventions should be applied as described in Fetal Evaluation Protocol (pages 14-16 of the Clinical Use Guide).